Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12452

0 - FRONT

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

COMPLAINT / INJURY REPORT

1. COMPLAINT NUMBER: STL 4058 1245Z
2. DATE OF COMPLAINT (Month / Day / Year): 7-3-97

3. FORM OF COMPLAINT
a.
(1) [X] TELEPHONE
(2) [ ] LETTER
(3) [ ] VISIT

4. SOURCE OF COMPLAINT
a.
(1) [X] CONSUMER (3) [ ] TRADE SOURCE
(2) [ ] GOVERNMENT (4) [ ] OTHER
[ ] L [ ] S [ ] F (Indicate In Remarks)

5. COMPLAINANT IDENTIFICATION
a. NAME AND ADDRESS (Include ZIP Code): [redacted]
b. AREA CODE AND TELEPHONE NUMBER
HOME ([redacted]
WORK ( )

6. COMPLAINT OR INJURY
a. DESCRIPTION OF COMPLAINT / INJURY
Complainant stated that her mother, [redacted] 59 years old and two other women purchased Omnitrim Diet Tea from a distributor who told them that along with losing weight, this tea would also help treat their high blood pressure. Complainant's mother used the tea approximately three weeks and then had a heart attack. One of the other women, [redacted] had to be ~~hospitalized~~ with stroke-like symptoms & was told that if it happened again, it would most likely be fatal. Ingredient statement listed (see remarks)

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?
(1) [ ] NO (2) [ ] YES
(If "Yes" Explain in Remarks)

7. INJURY OR ILLNESS RESULTED
(1) [ ] NO
(2) [X] YES *
*(If "yes" complete items a through d)

a. EIB (HFC - 161) NOTIFIED
(1) [ ] ~~N/C~~ ~~YES~~
(2) [X] ~~Yes~~ ~~NO~~
DATE: faxed 7-7-97

b. TYPE SYMPTOMS — ONSET (HR.)
(1) [ ] VOMITING
(2) [ ] NAUSEA
(3) [ ] DIARRHEA
(4) [ ] FEVER
(5) [ ] SKIN/EYE IRR.
(6) [ ] HEADACHE
(7) [X] OTHER: heart attack

c. ATTENDING HEALTH PROFESSIONAL?
(1) [ ] NO (2) [X] YES
(If "Yes" give name, address, and phone number) [redacted]

d. HOSPITALIZATION REQUIRED?
(1) [ ] NO (2) [X] YES
(If "Yes" give name, address, phone number and dates) [redacted]
6/19-30/97

8. PRODUCT AND LABELING
a. BRAND NAME: Omnitrim
b. PRODUCT NAME: Diet Tea
c. SIZE AND PACKAGE TYPE: .4 oz paper pkg (powder)
d. NAME AND LOCATION OF STORE WHERE PURCHASED: Dist: [redacted]
e. PACKAGE CODE / SERIAL NUMBER / ETC.: V7142 64541
EXP. / USE BY DATE:
f. DATE PURCHASED: within past month
g. PRODUCT USED (If "Yes" enter date) (1) [ ] NO (2) [X] YES Date:
h. AMT. REMAINING: some

9. MANUFACTURER / DISTRIBUTOR OF PRODUCT
a. HOME DISTRICT: DAL-DO
b. C.F. NO.: 1643750
c. NAME AND LOCATION OF FIRM (Include ZIP Code): Omnitrition International, Inc. Carrollton, TX 75006
d. IMPORT PRODUCT
(1) [ ] NO
(2) [ ] YES

10. EVALUATION AND DISPOSITION
a. PROBLEM KEY WORD
(1) CODE: RX
(2) DESCRIPTION: heart attack

b. EVALUATION
(1) [ ] NOT AN FDA OBLIGATION
(2) [ ] OBLIGATION, NO VIOLATION
(3) [X] FDA ACTION INDICATED
(4) [ ] INSUFFICIENT INFORMATION UNABLE TO EVALUATE

b. DISPOSITION
(1) [X] IMMEDIATE FOLLOW-UP
(2) [ ] F / U NEXT EI
(3) [ ] CLOSED WITHOUT FURTHER INVESTIGATION
(4) [ ] REFERRED TO OTHER FEDERAL AGENCY (Closes File)
(5) [ ] REFERRED TO STATE / LOCAL AGENCY (Closes File)
(6) [ ] REFERRED TO OTHER FDA _____ DISTRICT
(7) [ ] REFERRED TO OCI

11. PRODUCT CODE: 54ECG09

12. INFORMATION COPIES TO:
[ ] HFM-660 [ ] HFZ-343
[ ] HFD-730 [ ] HFC-161
[ ] HFV-210 [ ] HFS-635
[ ] OTHER _____

13. REMARKS
Ephedra 20 mgs. Complainant wants to know how FDA can let product be sold.

MEDWATCH FORMS MAILED 7-7-97.

14. NAME AND TITLE OF DISPOSITION OFFICIAL
Dottie Block/CSI/CCC

15. DATE
7-7-97

FORM FDA 2516 (5/94)
*U S GPO 1994-301-026/00410
85

000001

COMPLAINT / INJURY FOLLOW-UP

1. COMPLAINT NUMBER: STL 4058

2. ACTION REQUESTED
(1) [X] INVESTIGATION
(2) [X] COLLECT SAMPLE
(3) [ ] INSPECTION
(4) [ ] OTHER

(a). REMARKS *(Additional details)*
Assignment 97-0205 Received from HFS-636 requesting investigation at complainant.

(b) REQUESTING OFFICIAL'S NAME AND TITLE: Gregory Dixon, SI, KAN-DO

(c) DATE REQUESTED: 7/15/97

(d) PRODUCT NAME: OmniTRIM Herbal Tea

3. ASSIGNED TO: Randy Baxter, CSO Springfield, MO RP

(a) DUE BY: 7/31/97

4. ACTION TAKEN
(1) [X] INVESTIGATION
(2) [X] SAMPLE COLLECTED
(3) [ ] INSPECTION
(4) [ ] NONE

(a) SAMPLE NUMBER(s): INV 97-688-870

(b) DESCRIPTION OF ACTION TAKEN

On 7/22/97 I contacted the complainant by phone and arranged to meet her at her residence later that [redacted] morning.

I arrived, interviewed Mrs. [redacted] collected 4 packets of the OmniTRIM Herbal Tea, and all promotional literature which accompanied her order. I then prepared a 2 page affidavit explaining the method & amount of product ingestion, symptoms, and listed all materials which were provided by Mrs. [redacted] I also obtained a signed medical release form and presented it to [redacted] 7/22/97 (MED RCDS will be forwarded when received.)

**During the interview I obtained information needed to contact a second person who had also experienced adverse reactions following use of the OmniTRIM product. The individual's name is [redacted] also of [redacted]

The product sample (INV 97-688-870 will be shipped to [redacted] 7/23/97 via FedEx. Medical Records, copy of collection report & attachments are to be shipped to HFS-636 OSN via KAN-DO.

(c) ACTION OFFICIAL'S NAME AND TITLE: Randy D. Baxter, CSO

(d) ACTION DISTRICT: KAN

(e) DATE COMPLETED: 7/22/97

5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE

(a) HOME DIST.: DAL

(b). CF NO.:

(C) NAME AND ADDRESS: OMNITRITION INTERNATIONAL, INC. CARROLLTON, TEXAX 75006 (972) 417-9200

6. PROGRAM DATA

(a) OPERATION: 13

(b) PAC: 21R801

(c) PRODUCT CODE: 31PDG99

(d) EMP. HOME DIST.: KAN

(e) EMP. NO.: 299

(f) POS CL.: 2

(g) HOURS: 8

7. EVALUATION
(0) [X] PENDING
(1) [ ] NO ACTION INDICATED (NAI)
(2) [ ] VOLUNTARY ACTION INDICATED (VAI)
(3) [ ] OFFICIAL ACTION INDICATED (OAI)
(4) [ ] NOT AN FDA OBLIGATION
(5) [ ] REFERRED TO HOME DISTRICT
(6) [ ] INSUFFICIENT INFO. UNABLE TO EVAL.

8. FINAL DISPOSITION
(1) [ ] FOLLOW-UP NEXT E I
(2) [ ] WARNING LETTER
(3) [ ] CITATION
(4) [ ] SEIZURE
(5) [ ] INJUNCTION/PROSECUTION
(6) [ ] REFERRED TO OTHER AGENCY *(Indicate Agency in Remarks)*
(7) [ ] RECALL
(8) [ ] NO ACTION

9. INFO. COPIES TO
[ ] HFB-100
[ ] HFD-730
[ ] HFV-236
[ ] HFZ-343
[ ] HFC-161
[ ] _____
_____
_____

REMARKS: Send to CFSAN for their evaluation — ephedrine produced

NAME AND TITLE OF DISPOSITION OFFICIAL: George H. VanWey ASI

DISPOSITION: KANDO

DISPOSITION DATE: 7/24/97

FORM FDA 2516a (1/90)

*U.S.GPO:1991-0-312-208/41637

000002

Adverse Reaction Questionnaire

[redacted]

Complaint Number: STL 4058

Investigator: R. D. BAXTER SPFD., MO RP

Consumer Information

Date of Report: 7/22/97 MM/DD/YY

Initial Report Source: ☐ORA Consumer Injury
☒Telephone ☐Correspondence ☐MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted]

Gender: ☒F ☐M

Age: 59

Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☐8-Other _____ ☐9-Unknown

Information on Adverse Reaction

Date of Adverse Reaction: 6/19/97
Previous Reaction to Product Type: ☐Yes ☒No

Give the site of consumption/ingestion (e.g. home, restaurant, office): HOME

The following information relates to the consumers' use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):
MRS. [redacted] started using product mid-MAY, started feeling BAD 6/18/97.

How long did the symptoms last? WENT TO HOSPITAL 6/19 - Quadruple Bypass performed 6/24/97.
Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.).
2 packets/day mixed w/ water (labeling recommends 3/day)

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:
CAPTOPRIL 100MG (1½ TABS 3X/day) (50mg/3X/day) HIGH B. PRESSURE

Did event abate after use of suspected product stopped or dose reduced: ☐Yes ☐No ☒Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☒Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☒Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No
Give health care provider's name, address and telephone number: [redacted]

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist
☐Other (specify) _____

What medical tests were performed and what were the results? ANGIOPLASTY + MED. RCDS. HAVE BEEN REQUESTED & will be forwarded to HFS-636.

What was the medical diagnosis? HEART ATTACK
What treatment(s) was given (e.g., drugs, other)? QUADRUPLE BYPASS @ [redacted]

Were there any preexisting condition(s)/treatment(s)?
(If YES, list them including allergies, and chronic diseases): ☒Yes ☐No HIGH BLOOD PRESSURE

Aff. #3 INV 97-688-870
7/22/97
RDB

Product Category

1. Adverse reaction to:
   - ☐ Medical Food (under medical supervision) ☐ Infant Formula
   - ☒ Dietary Supplement (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands, garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
   - ☐ Other (traditional food) VITAMIN FORTIFIED HERBAL TEA w/ EPHEDRINE (20mg)

Other Product Problems

2. ☐ Foreign Object (specify): _____
3. ☐ Other (specify): _____

Information on Suspected/Alleged Product

Give the product name as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):

OMNITRITION'S
OMNITRIM EXTRA
VITAMIN FORTIFIED HERBAL TEA
NET WT .4 OZ (11gm)

DIRECTIONS: Place one packet in 4 to 8 oz. water. Take 30 minutes before meals (3x/day). Begin w/ 1 serving/day & increase to 3 servings/day over period of 7 to 10 days.

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):

☐ Check here if ingredients are unknown

EACH PACKET CONTAINS NO MORE THAN 20mg of ephedrine.

VITAMIN A, VITAMIN C, E, Red TEA EXTRACT, Tyrosine, Taurine, Ferulic Acid

If a particular ingredient is suspected of contributing to the reaction, please indicate the appropriate category below:

- ☐ Aspartame
- ☐ Monosodium Glutamate
- ☐ Sulfite
- ☒ Other EPHEDRINE * (20mg/serving)
- ☐ Unknown
- ☐ Color Additive (please specify) _____

Is the product label available, if yes submit a quality copy along with this questionnaire: ☒ Yes ☐ No ☐ Unknown

Product Sample Available: ☒ Yes ☐ No ☐ Unknown 97-688-870

Outcome Attributed to Adverse Event:

(If yes, include pertinent medical records)

Death: ☐ Yes ☒ No

Life-Threatening: ☒ Yes ☐ No

Hospitalization: ☒ Yes ☐ No (if YES, indicate if initial or prolonged) _____

Required intervention to prevent permanent impairment/damage: ☒ Yes ☐ No

Did the adverse reaction result in a congenital anomaly: ☐ Yes ☐ No UNKNOWN

000004

Att. #3 INV 97-688-870

AKMS # 12452

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
KANSAS CITY DISTRICT

MEMORANDUM

Date: August 25, 1997

To: CFSAN/Division of Field Program Planning and Evaluation (HFS-636) ATTN: Adverse Reaction Monitor

From: Randy D. Baxter, CSO [redacted]

Subj: OmniTRIM Herbal Tea w/ ephedrine reaction F/U (Project #12452 KAN-DO Assignment 97-0205)

Dealer: [redacted] Dist: [redacted]

On 7/22/97 I visited the residence of Mrs. [redacted] @ the above listed address. Mrs. [redacted] provided information regarding the purchase and use of the herbal tea w/ ephedrine. Mrs. [redacted] also explained her medical condition which she believes was caused as a result of ingestion of the OmniTrim product.

During this visit I obtained Mrs. [redacted] authorization for medical records disclosure. The disclosure and all medical records are attached as Att.# 1, 24 pages. Medical records were provided by [redacted]. Also attached are copies of forms 2516 & 2516a, IOM 910-D, Omnitrition promotional literature, and a 2 page affidavit signed by [redacted]

I also visited Ms. [redacted] (see 2516) 7/24/97. Ms. [redacted] stated her medical conditions were brought on by stress due to a number of personal problems, not the herbal products. Ms. [redacted] also reported she was not hospitalized as is stated in the Complaint/Injury Report. Ms. [redacted] continues to use and sell Omnitrition's products, stating the tea and coffee drinks give her energy and make her feel great.

Randy D. Baxter, CSO
[redacted]

O: HFS-636
cc: [redacted]
cc:

97 AUG 28 P3:23

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-452

TO: Lori A. Love, M.D.
CRRS

FROM: Constance J. Hardy, R.D.
DPEP

DATE: April 15, 1999

SUBJECT: AEMS12452

I spoke to [redacted], the sister or [redacted] today concerning her sister's use of the product OmniTrim. She stated she is her sister's babysitter and that she only took 1 package of the product at a time.

File name: [redacted]